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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,456	07/11/2003	Mongkol Sriwongjanya	141-287	3239

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/617,456	SRIWONGJANYA ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-65 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-65 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 09/15/03.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Corrected Filing Receipt filed 07/10/06, Information Disclosure Statement filed 09/15/03.

Claims 1-65 are pending. Claims 1-63 are drawn to a controlled release metoprolol composition. Claims 64 and 65 are drawn to a method for preparing said composition.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 8, 9, 12, 13, 17-20, 27, 28, 30-32, 49-54, 56, 57, 61, 64 and 65 are rejected under 35 U.S.C. 102(e) as being anticipated by Chen et al. USPN 7,022,342.

Chen discloses an oral controlled release capsule comprising: 1) a core comprising a β-adrenergic blocking agent, an inert pellet, a binder, and a filler; and 2) a coating comprising a water-insoluble polymer, a water soluble polymer, a plasticizer, and an anti-sticking agent (column 1, lines 8-18; and column 3, lines 6-30). β-adrenergic blocking agent includes metoprolol. Inert pellet as a starting material can be any type of commonly known pellet including starch or sugar sphere having diameter

from about 15-50 mesh. Binder includes hydroxypropyl methylcellulose (column 4, lines 16-42). Water-insoluble polymer includes cellulose acetate butyrate. Plasticizing agent includes well-known pharmaceutically acceptable agents (column 5, lines 10-56). Chen further discloses the process for preparing the oral controlled release dosage form comprising forming a suspension of the binder, drug and other ingredients, layering the suspension onto the inert pellet using any of the layering techniques known in the art such as fluidized bed coating, rotor granulation or pan coating, and layering the controlled release coating layer by any means commonly known in the art (column 5, lines 3-9, and 57-64). The claimed release profiles, as well as the C_{max} values are disclosed in columns 6 and 9.

It is noted that independent claim 49 requires channeling agent. However, the specific channeling agent is not recited in this claim. Therefore, Chen is relied upon for the teaching of filler (channeling agent) having particle size of about 20 μm, such as microcrystalline cellulose (column 4, lines 48-51).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 8, 9, 12, 13, 17-23, 27-54, 56, 57 and 60-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. USPN 7,022,342, in view of Sriwongjanya et al. WO 99/61005.

Chen is relied upon for the reason stated above. Chen does not teach the channeling agent in the controlled release coating layer.

Sriwongjanya teaches a controlled release oral dosage in the form of tablet or pellet comprising an active core, and a controlled release coating layer comprising channeling agent such as methacrylic acid copolymer (page 8, lines 5-19). The dosage form further comprises an immediate release tablet or pellet containing active drug. The controlled release and immediate release tablets or pellets are placed in a hard gelatin capsule for administration to animal or human (page 5, lines 4-10; and page 10, lines 6-9). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the controlled release dosage of Chen to include the immediate release dosage form and the channeling agent in view of the teachings of Sriwongjanya, because Sriwongjanya teaches channeling agent increases the volume of fluid imbibed into the core and creates channels to enable the dosage form to dispense the drug (page 8, lines 7-9), because Sriwongjanya teaches a controlled release dosage form that is easy to manufacture and can be used to prepare a range of dosing levels, because Sriwongjanya teaches a controlled release dosage form having similar C_{max} value and release profile as desired by Chen (page 3, lines 21-27), and because Chen teaches the desirability to obtain a controlled release dosage form characterized by a high extent of absorption, and a high bioavailability that can provide

therapeutic levels of the drug to a subject in need of such treatment over a twelve to twenty-four hour period (column 2, lines 59-67).

Claims 7, 10, 11, 14-16, 24-26, 49, 55, 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. USPN 7,022,342, in view of Patel et al. US 6,569,463.

Chen is relied upon for the reasons stated above. Chen does not teach the claimed surfactant in the core composition.

Patel teaches a solid pharmaceutical composition comprising a solid carrier including a substrate and an encapsulation coat comprising active drugs and surfactants (abstract). Surfactant includes tween 80 (polysorbate 80) (tablet 11 at column 19, line 12). The substrate includes pellet, bead, or the like such as sugar or microcrystalline cellulose (column 28, lines 20-40). The solid carrier is further coated with a delayed release coating comprising an enteric polymer, plasticizer, and surfactant (column 34, lines 38-50; and column 35, lines 1-67). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the controlled release dosage of Chen to include the surfactant in view of the teaching of Patel, because Patel teaches using surfactant to increase solubility, improve dissolution, enhance absorption and bioavailability of the active ingredient in the solid carrier (column 9, lines 63 through column 10, lines 1-17), because Patel teaches a dosage form suitable for metoprolol (column 8, line 31), and because Chen teaches the

desirability to obtain a controlled release dosage form characterized by a high extent of absorption, and a high bioavailability (column 2, lines 59-67).

It is noted that the cited references do not explicitly teach the claimed inert core diameter of about 60-80 mesh. However, it would have been obvious to one of ordinary skill in the art to, by routine experimentation optimize the inert core size to obtain the claimed invention, because Chen teaches an inert core having size of about 50 mesh, and because Patel teaches any pharmaceutically known inert core.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chang et al., and Mulye are cited as of interest for the teachings of controlled release dosage form of metoprolol.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S. Tran
Patent Examiner
Art Unit 1615